

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

### WRITTEN OPINION

(PCT Rule 66)

To:  
HELEN C. LOCKHART  
WOLF, GREENFIELD & SACKS, P.C.  
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BOSTON, MA 02210

Date of Mailing (day/month/year) **23 MAY 2003**

Applicant's or agent's file reference  
C00989/70017

REPLY DUE within 2 months/days from the above date of mailing

International application No. PCT/US02/17124	International filing date (day/month/year) 31 May 2002 (31.05.2002)	Priority date (day/month/year) 06 June 2001 (06.06.2001)
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International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 21/64 and US Cl.: 436/94, 164, 172; 435/6

Applicant  
U.S. GENOMICS, INC.

	Initials
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1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - ☒ Basis of the opinion
  - ☐ Priority
  - ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☐ Certain observations on the international application

**DOCKETED**  
**MAY 28 2003**

3. The applicant is hereby **invited to reply** to this opinion.
 

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.  
For an informal communication with the examiner, see Rule 66.6

**If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 06 October 2003 (06.10.2003).

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Jan M. Ludlow Telephone No. (703) 308-0661
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WRITTEN OPINION

International application No.

PCT/US02/17124

**I. Basis of the opinion**

1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
 pages 1-26, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
 pages 27-32, as originally filed  
 pages NONE, as amended (together with any statement) under Article 19  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
 pages 1-12, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
 pages NONE, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

**WRITTEN OPINION**

International application No.  
PCT/US02/17124

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>4-8, 13-14, 16-17, 19-21, 23-24</u>	YES
	Claims <u>1-3, 9-12, 15, 18 and 22</u>	NO
Inventive Step (IS)	Claims <u>4-8, 13-14, 16-17, 19-21, 23-24</u>	YES
	Claims <u>1-3, 9-12, 15, 18, 22</u>	NO
Industrial Applicability (IA)	Claims <u>1-24</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3, 9-12, 15, 18, 22 lack novelty under PCT Article 33(2) as being anticipated by WO98/10097.

WO 98/10097 teaches a method for determining the velocity of DNA using fluorescent measurement at two different locations in a flow path as claimed.

Claims 4-8, 13-14, 16-17, 19-21, 23-24 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the instant method of measuring velocity of an elongated polymer in which the signal has a center-of-mass, contour center, leading edge and leading-edge-rise-time, or the instant method of determining velocity including determining the length of the polymer or distance between two points on the polymer.

Claims 1-24 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

WRITTEN OPINION

International application No.  
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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.